AUG - 3 2001

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

in Accordance with SMDA of 1990

ANTERIOR CRUCIATE LIGAMENT (ACL) INSTRUMENT SYSTEM

April 3, 2001

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

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800-258-1946 (phone)
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TRADE NAME: **Anterior Cruciate Ligament (ACL) Instrument System**

COMMON NAME: ACL Instrument System

DEVICE CLASS: CLASS II

PRODUCT CODE: HWC
CLASSIFICATION: **SCREW, FIXATION, BONE, NON-SPINAL**
REVIEW PANEL: Orthopedics

INTENDED USE

The ACL Instrument System is intended for use in arthroscopic reconstruction of cruciate ligaments. This system includes a suture disk intended for use in the fixation of soft tissue with sutures to bone for ruptures of the anterior cruciate ligament.

DEVICE DESCRIPTION

Aesculap's Anterior Cruciate Ligament (ACL) Instrument system is a complete instrument set for minimal invasive ACL reconstruction. It is comprised of a variety of non-sterile, surgical grade stainless steel, instruments such as femoral reamers: 5.5-11 mm at ½ increments; tibial drills: 5.5-11mm increments, tissue protection sleeves: 5.5 – 11mm at ½ increments, aiming devices, tendon stripper, k-wires, forceps, needle holder, and suture board. The suture board supports easy and simple transplant preparation. The system also includes surgical grade titanium implants including a suture plate and 2 suture disks. The suture disk is provided sterile.

PERFORMANCE DATA

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act. The new ACL Instrument System conforms to applicable ASTM and ISO standards.

SUBSTANTIAL EQUIVALENCE

The Anterior Cruciate Ligament (ACL) Instrument System is substantially equivalent in their intended use, labeling, and basic operating principles to the following predicate devices:

- Acufex Microsurgical's Acuflex Levy ACL Drill Guide System (K832277)
- Smith & Nephew's (ACL) Surgical Instruments (K934044)
- Stryker ACL Interference Screw System (K952460)
- Smith & Nephew's Suture Lock (K964935)
- AcuFex's Fixation Button (K884565)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 2001

Ms. Lisa M. Millington
Regulatory Associate
Aesculap, Inc.
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K011102
Device Name: Anterior Cruciate Ligament (ACL) Instrument System
Regulation Number: 21 CFR 888.3040
Regulatory Class: II
Product Code: HWC
Dated: July 13, 2001
Received: July 16, 2001

Dear Ms. Millington:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K011102

Device Name: Anterior Cruciate Ligament (ACL) Instrument System

Indication for Use:

The ACL Instrument System is intended for use in arthroscopic reconstruction of cruciate ligaments. This system includes a suture disk intended for use in the fixation of soft tissue with sutures to bone for ruptures of the anterior cruciate ligament.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011102

Prescription Use ✓ or Over-the-Counter Use _____

(per 21 CFR 801.109)

(Optional Format 3-10-98)